K061517

October 10, 2006

PRE-MARKET NOTIFICATION 510 (K) SUMMARY

(As Required by 21 CFR 807.92)

Prime Herbs Co.,
754 San Aleso Avenue
Sunnyvale, CA 94085
Phone: 408-744-1077
Genevieve Hsia

NOV 2 2 2006

Device Name: Precision Press Tack / Intraderm Needle, Precision Seven Star Needle, Präzision Acupuncture Needle, Alpha Acupuncture Needle, Fine Point Acupuncture Needle, Chi Acupuncture Needle and Zen Acupuncture Needle
Common Device Name: Acupuncture Needle, Signal Use
Product Code: MQX
Medical Specialty: General Hospital
Device Class: II

Precision Press Tack / Intraderm Needles, Precision Seven Star Needles, Präzision Acupuncture Needles, Alpha Acupuncture Needles, Fine Point Acupuncture Needles, Chi Acupuncture Needles and Zen Acupuncture Needles are defined as prescription devices intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.

FDA had issued 510(K)s to 47 different signal use acupuncture Needless brand and them have been used for general practice of acupuncture in the United States since 1996. We had searched Federal Consumer Information Center web site http://www.pueblo.gsa.gov and U.S. Consumer Product Safety Commission web site http://www.cpsc.gov and found no serious or We threatening accidents involving acupuncture Needless.

Precision Press Tack / Intraderm Needles, Precision Seven Star Needles, Präzision Acupuncture Needles, Alpha Acupuncture Needles, Fine Point Acupuncture Needles, Chi Acupuncture Needles and Zen Acupuncture Needles are sterile, single use only. The design, material used, sterility and biocompatibility of this acupuncture Needles meet the general specifications and criteria for an single use acupuncture Needles and is effective for the practice of acupuncture.

In conclusion, based on the information provided with this 510(K) Notification, the Precision Press Tack / Intraderm Needles, Precision Seven Star Needles, Präzision Acupuncture Needles, Alpha Acupuncture Needles, Fine Point Acupuncture Needles, Chi Acupuncture Needles and Zen Acupuncture Needles meet the criteria for 510(k) acceptance. The Precision Press Tack / Intraderm Needles, Precision Seven Star Needles, Präzision Acupuncture Needles, Alpha Acupuncture Needles, Fine Point Acupuncture Needles, Chi Acupuncture Needles and Zen Acupuncture Needles are equivalent to other acupuncture Needless which are currently being sold through interstate commerce.

Genevieve Hsia, President

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Genevieve Hsia
President
Prime Herbs Corporation
754 San Aleso Avenue
Sunnyvale, California 94085

NOV 2 2 2006

Re: K061517
Trade/Device Name: Fine Point Acupuncture Needle, Alpha Acupuncture Needle, Prazision Acupuncture Needle, Zen Acupuncture Needle, Chi Acupuncture Needle, Precision Press Tack, Precision Intradermal Needle and Seven Star Needle
Regulation Number: 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: MQX
Dated: October 19, 2006
Received: October 19, 2006

Dear Ms. Hsia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061517

Device Name: Fine Point Acupuncture Needle, Alpha Acupuncture Needle, Prazision Acupuncture Needle, Zen Acupuncture Needle, Chi Acupuncture Needle, Precision Press Tack, Precision Intradermal Needle, & Seven Star Needle

Indications For Use: To pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brigitte Y. Michaud MD

...of Anesthesiology, General Hospital...

...ion Control, Dental Devices

K 061517